



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2010-0078; FRL-9348-7]

#### **Killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup>; Exemption from the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> in or on all food commodities when applied as a pre- or post-emergent herbicide and used in accordance with good agricultural practices. Marrone Bio Innovations, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> under the FFDCA.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### **SUPPLEMENTARY INFORMATION).**

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2010-0078, is at <http://www.regulations.gov> or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in

EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

Some documents cited in this final rule are located in a different docket associated with a notice of receipt (NOR) of an application for a new pesticide, *Streptomyces acidiscabies* strain RL-110T, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). That docket number is EPA-HQ-OPP-2010-0079. Such documents include the Biopesticides Registration Action Document (BRAD) provided as a reference in Unit IX. (Ref. 1) of this final rule, and other documents listed Unit IX. of this final rule.

**FOR FURTHER INFORMATION CONTACT:** Ann Sibold, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6502; e-mail address: [sibold.ann@epa.gov](mailto:sibold.ann@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl). To access the harmonized test guidelines referenced in this document electronically, please go to <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0078 in the subject line on the first page

of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0078, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

## **II. Background and Statutory Findings**

In the **Federal Register** of March 10, 2010 (75 FR 11171) (FRL-8810-8), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 0F7681) by Marrone Bio Innovations, Inc., 2121 Second St., Suite B-107, Davis, CA 95618. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Streptomyces acidiscabies* strain RL-110<sup>T</sup>. This notice referenced a summary of the petition prepared by the petitioner, Marrone Bio Innovations, Inc., which is available in the docket via <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance exemption and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue.... ” Additionally, section 408(b)(2)(D) of FFDCA requires

that EPA consider “available information concerning the cumulative effects of [a particular pesticide’s] . . . residues and other substances that have a common mechanism of toxicity.”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

### **III. Toxicological Profile**

Consistent with section 408(b)(2)(D) of FFDCA, EPA reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

#### *A. Overview of *Streptomyces acidiscabies* strain RL-110<sup>T</sup>*

*Streptomyces* species are commonly found in agricultural settings (i.e., soils and decaying plant material) and are present on fresh produce of all kinds with no known adverse effects. Indeed, the Manual of Clinical Microbiology (9<sup>th</sup> edition) (Ref. 2) states that the primary ecological niche for aerobic actinomycetes, such as *Streptomyces acidiscabies* strain RL-110<sup>T</sup>, is likely decaying plant material. The Manual of Clinical Microbiology (9<sup>th</sup> edition) (Ref. 2) further states that infections caused by *Streptomyces* species are infrequent and limited to species unrelated to *acidiscabies* and does not identify *Streptomyces acidiscabies* as clinically significant. No food borne disease outbreaks

associated with *Streptomyces* species or mammalian active toxin production from *Streptomyces* species, including *Streptomyces acidiscabies*, have been reported.

*Streptomyces* species have been used in pesticide products to control various pests of agricultural products. In conjunction with the registration of some of these pesticide products, EPA established the following exemptions from the requirement of a tolerance:

1. *Streptomyces* sp. (now *griseoviridis*) strain K61 (40 CFR 180.1120) – See the **Federal Register** of April 21, 1993 (58 FR 21402) (FRL-4577-9).
2. *Streptomyces lydicus* WYEC 108 (40 CFR 180.1253) – See the **Federal Register** of June 3, 2004 (69 FR 31297) (FRL-7361-3).

*Streptomyces acidiscabies* strain RL-110<sup>T</sup> was isolated from scab-infected potatoes in Maine and New York. The pesticide active ingredient consists of killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> cells and spent fermentation media. Thaxtomin A, a phytotoxin produced by *Streptomyces acidiscabies* strain RL-110<sup>T</sup>, provides the herbicide mode of action.

#### *B. Microbial Pesticide Toxicology Data Requirements*

All applicable mammalian toxicology data requirements supporting the request for an exemption from the requirement of a tolerance for residues of killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> in or on all food commodities have been fulfilled with data submitted by the petitioner or data waiver requests that have been granted by EPA. Results of acceptable (i.e., data that are scientifically sound and useful for risk assessment) toxicity tests (acute oral, dermal, and inhalation toxicity), primary eye and dermal irritation tests, and a skin sensitization test, all of which addressed potential routes of exposure to the active ingredient, revealed little to no toxicity,

irritation, or sensitization attributed to killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup>. Moreover, the acute toxicity and primary irritation tests received a Toxicity Category IV classification (see 40 CFR 156.62). Finally, the results of an acute intravenous injection toxicity/pathogenicity test demonstrated that live *Streptomyces acidiscabies* strain RL-110<sup>T</sup> were not toxic, infective and/or pathogenic to the test animals.

The overall conclusions from all toxicological information submitted by the petitioner are briefly described in this unit, while more in-depth synopses of some study results can be found in the associated Biopesticides Registration Action Document (BRAD) provided as a reference in Unit IX. (Ref. 1).

1. *Acute oral toxicity/pathogenicity (Harmonized Guideline 885.3050) and acute pulmonary toxicity/pathogenicity (Harmonized Guideline 885.3150) (Master Record Identification Number (MRID No.) 479468-17).* EPA waived the acute oral toxicity/pathogenicity and acute pulmonary toxicity/pathogenicity data requirements for the killed microorganism, but required the intravenous injection acute toxicity/pathogenicity study to verify the product, under a “worst case” scenario, would not be toxic and/or pathogenic to the test animals.

The toxicity component of the acute oral toxicity/pathogenicity and acute pulmonary toxicity/pathogenicity data requirements was fulfilled by MRID No. 479468-02 (acute oral toxicity, described in this unit) and MRID No. 479468-04 (acute inhalation toxicity, described in this unit), respectively.

2. *Acute injection toxicity/pathogenicity (intravenous) – rat (Harmonized Guideline 885.3200; MRID No. 479468-08).* An acceptable acute injection toxicity/pathogenicity

study demonstrated that live *Streptomyces acidiscabies* strain RL-110<sup>T</sup> was not toxic, infective, and/or pathogenic to rats when administered intravenously in a single dose of  $9.0 \times 10^6$  colony-forming units (CFU) per rat.

3. *Acute oral toxicity – rat (Harmonized Guideline 870.1100; MRID No. 479468-02)*. An acceptable acute oral toxicity study with a test substance containing killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> demonstrated that the oral median lethal dose (LD<sub>50</sub>) (i.e., a statistically derived single dose that can be expected to cause death in 50% of test animals) was greater than 5,000 mg/kg for female rats. This is the limit dose, and no further acute oral testing is required. (Toxicity Category IV).

4. *Acute dermal toxicity – rat (Harmonized Guideline 870.1200; MRID No. 479468-03)*. An acceptable acute dermal toxicity study with a test substance containing killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> demonstrated that the dermal LD<sub>50</sub> was greater than 5,050 mg/kg for male and female rats combined. This is the limit dose, and no further acute dermal testing is required. (Toxicity Category IV).

5. *Acute inhalation toxicity – rat (Harmonized Guideline 870.1300; MRID No. 479468-04)*. An acceptable acute inhalation study with a test substance containing killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> demonstrated that the inhalation median lethal concentration (LC<sub>50</sub>) was greater than 2.21 mg/L (the limit or maximum dose required to be tested) for male and female rats combined. (Toxicity Category IV).

6. *Primary dermal irritation – rabbit (Harmonized Guideline 870.2500; MRID No. 479468-06)*. An acceptable primary dermal irritation study demonstrated that a test substance containing killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> was not irritating to the skin of rabbits (Toxicity Category IV).

7. *Skin sensitization – guinea pig (Harmonized Guideline 870.2600; MRID No. 479468-07)*. An acceptable dermal sensitization study demonstrated that a test substance containing killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> was not a dermal sensitizer to guinea pigs.

#### **IV. Aggregate Exposure**

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

##### *A. Dietary Exposure*

1. *Food exposure*. Killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> will be applied as a herbicide to agricultural crops pre-plant, at-plant and post-plant and may be applied up to the day of harvest. Exposure to this active ingredient through food is possible but is expected to be minimal for the following reasons:

- i. The proposed pesticide product will be diluted prior to application.
- ii. Pre-plant applications will occur 1-45 days or more before planting.
- iii. At-plant applications will be broadcast and incorporated into the soil mechanically or by rainfall or sprinkler application.
- iv. Post-plant applications for trees will be made as a broadcast or banded application to soil surface below established trees or between tree rows and incorporated into the soil by rainfall, irrigation or mechanical incorporation.

- v. Post-plant lay-by and split application will be made between rows and incorporated into the soil.
- vi. Application to rice fields is followed by flooding or partially draining and re-flooding the fields. and
- vii. Rainfall and sprinkler irrigation will further wash residues of the pesticide from treated crops.

Following all applications, killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> will naturally degrade due to consumption by other biological organisms, including bacteria and fungi (Ref. 3).

In the unlikely event that any residues of the pesticide remain in or on consumed food, no adverse effects would be expected, based on the lack of toxicity, infectivity, and/or pathogenicity demonstrated in the submitted studies.

2. *Drinking water exposure.* Exposure to residues of killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> in consumed drinking water is unlikely, since the majority of the proposed use patterns (ground and aerial) include measures to incorporate the herbicide into the soil; however, residues may appear at low levels in ground and surface water from these uses due to runoff or drainage from treated fields, or by spray drift. These residues will be minimized by natural degradation of the active ingredient by microbial activity (Ref. 3). Furthermore, since application of the product is concentrated in upper soil strata, movement through the soils would likely filter out any remaining product.

The proposed directions for applications to established turf in landscapes provide for dilution of the product prior to application, but do not include measures to incorporate the

product. Since established turf constitutes significant ground cover, this, in itself, would be expected to reduce the potential runoff of the pesticide into surface water and percolation to ground water. The proposed directions for applications to ornamentals in landscapes specify dilution prior to application and incorporation by irrigation or raking into the soil. These measures, along with natural degradation and incorporation of the product into upper soil strata, will reduce the potential for runoff into surface or ground water.

The proposed use in rice provides the greatest potential for residues of killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> to appear in ground and surface water, since application to rice fields is followed by flooding the treated fields. If residues of *Streptomyces acidiscabies* strain RL-110<sup>T</sup> are transferred to surface or ground waters that are intended for eventual human consumption, and subjected to sanitation (e.g., chlorination, pH adjustments, filtration, high temperatures) in drinking water treatment plants, the residues would likely be removed from the finished drinking water (Ref. 4). In the unlikely event that any residues of the pesticide occur in drinking water even after being processed at a water treatment facility, no adverse effects would be expected, based on the lack of toxicity and pathogenicity demonstrated in the submitted studies.

#### *B. Other Non-Occupational Exposure*

Given the natural occurrence of *Streptomyces acidiscabies* in soil (Refs. 5 and 6), non-occupational and residential exposure may already be occurring. Application of killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> to established turf in residential and landscape settings will result in exposure via the dermal and inhalation routes. Any such exposures are expected to be minimal, since the concentration of killed, nonviable

*Streptomyces acidiscabies* strain RL-110<sup>T</sup> is diluted prior to application and the active ingredient is not expected to persist (see the food and drinking water exposure sections in this unit).

In the unlikely event that the proposed uses of the pesticide result in residential, non-occupational exposure, no adverse effects would be expected, based on the lack of toxicity, irritation and sensitization demonstrated in available data (see additional discussion in Unit III.).

#### **V. Cumulative Effects from Substances with a Common Mechanism of Toxicity**

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance exemption, EPA consider “available information concerning the cumulative effects of [a particular pesticide’s] . . . residues and other substances that have a common mechanism of toxicity.”

EPA has not found killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> to share a common mechanism of toxicity with any other substances, and killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, EPA has assumed that killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine chemicals that have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

#### **VI. Determination of Safety for U.S. Population, Infants and Children**

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor. In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Based on the acute toxicity and pathogenicity data discussed in Unit III.B., EPA concludes that there are no threshold effects of concern to infants, children or adults when killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> is used as labeled in accordance with good agricultural practices. As a result, EPA concludes that no additional margin of exposure (safety) is necessary.

Moreover, based on the same data and EPA analyses as presented in this unit, the Agency is able to conclude that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> when it is used as labeled and in accordance with good agricultural practices as a pre- or post-emergent herbicide. Such

exposure includes all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has arrived at this conclusion because, considered collectively, the data and information available on killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> do not demonstrate toxic potential to mammals, including infants and children.

## **VII. Other Considerations**

### *A. Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes for the reasons stated in this document and because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. In this context, EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup>.

### *C. Revisions to Requested Tolerance Exemption*

In the **Federal Register** of March 10, 2010, EPA announced Marrone Bio Innovations, Inc.'s filing of a pesticide petition that proposed establishing an exemption from the requirement of a tolerance for residues of *Streptomyces acidiscabies* strain RL-110<sup>T</sup> in or on all agricultural commodities. Two modifications have been made to the requested tolerance exemption. First, based upon the data and information available to the Agency, EPA is adding the qualifiers “killed” and “nonviable” before the microorganism’s taxonomic name and unique identifier. Use of these qualifiers is now consistent with the representation of this active ingredient in other associated regulatory documents and should assist in preventing confusion regarding its nomenclature in the future. Second, EPA is changing “in or on all agricultural commodities” to “in or on all food commodities” to align with the terminology the Agency currently uses when establishing tolerance exemptions for residues of other like active ingredients.

### **VIII. Conclusions**

EPA concludes that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup>. Therefore, an exemption from the requirement of a tolerance is established for residues of killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> in or on all food commodities when applied as a pre- or post-emergent herbicide and used in accordance with good agricultural practices.

### **IX. References**

1. U.S. EPA. 2012. Biopesticides Registration Action Document Killed, Nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> Revised April 22, 2012 (available as

“Supporting & Related Material” within docket ID number EPA-HQ- OPP-2010-0079 - 0019 at <http://www.regulations.gov>).

2. Murray, PR, EJ Baron, JH Jorgensen, ML Landry, MA Pfaller, editors. 2007. Manual of Clinical Biology. Vol.1. 9<sup>th</sup> Ed. Washington (DC): ASM Press.

3. Doumbou CL, Akimov V, Beaulieu C. 1998. Selection and characterization of microorganisms utilizing thaxtomin A, a phytotoxin produced by *Streptomyces scabies*. *Applied and Environmental Microbiology* 64:4313-4316.

4. Centers for Disease Control and Prevention. 2009. Drinking Water - Water Treatment. Available from [http://www.cdc.gov/healthywater/drinking/public/water\\_treatment.html](http://www.cdc.gov/healthywater/drinking/public/water_treatment.html).

5. Faucher E, Savard T, Beaulieu C. 1992. Characterization of actinomycetes isolated from common scab lesions on potato-tubers. *Canadian Journal of Plant Pathology* 14:197-202.

6. Loria R, Kers J, Joshi M. 2006. Evolution of plant pathology in *Streptomyces*. *Annual Review of Phytopathology* 44:469-487.

## **X. Statutory and Executive Order Reviews**

This final rule establishes a tolerance exemption under section 408(d) of FFDCA in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), or

Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded

mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require EPA consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

#### **XI. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: April 25, 2012.

Steven Bradbury,  
*Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Section 180.1314 is added to subpart D to read as follows:

**§ 180.1314 Killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup>; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of killed, nonviable *Streptomyces acidiscabies* strain RL-110<sup>T</sup> in or on all food commodities when applied as a pre- or post-emergent herbicide and used in accordance with good agricultural practices.

[FR Doc. 2012-14243 Filed 06/12/2012 at 8:45 am; Publication Date: 06/13/2012]